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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR             | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/677,672      | 10/02/2000  | Jean-Christophe Francis Audonnet | 454313-3160         | 3424             |

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EXAMINER

NGUYEN, DAVE TRONG

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1632     |              |

DATE MAILED: 01/17/2003

*DA* *11*

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |                                 |
|------------------------------|--------------------------------------|---------------------------------|
| <b>Office Action Summary</b> | Application No.<br><b>09/677,672</b> | Applicant(s)<br><b>Audonnet</b> |
|                              | Examiner<br><b>Dave Nguyen</b>       | Art Unit<br><b>1632</b>         |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)  Responsive to communication(s) filed on Oct 28, 2002

2a)  This action is FINAL.      2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

4)  Claim(s) 1-14 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-14 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some\* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)      4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)      5)  Notice of Informal Patent Application (PTO-152)

3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4      6)  Other: \_\_\_\_\_

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Applicant's election of Group I claims, drawn to a DNA vaccine comprising a naked DNA encoding an antigenic polypeptide and one adjuvant compound which is the polymers of acrylic or methacrylic acid, and of the species equine influenza virus and allysucrose in the response filed October 28, 2002, is acknowledged. The traversal with respect to the group restriction is found persuasive, and thus, the group restriction has been withdrawn by the examiner. The traversal with respect to the species restriction between equine rhinopneumonia virus and equine influenza virus is found persuasive. However, the traversal with respect to the species restriction of among all other pathogens is found unpersuasive because of the laundry list of members of pathogens as cited in claim 9. Applicant asserts that the members of claim 9 are not "too great in numbers", however, the examiner maintains that a search of one species, which is distinct in structure, within the context of DNA vaccine, does not necessarily overlap with that of another. In order to do complete an office action should a prior art rejection be applicable, the examiner has to search for all 37 members of the Markush group and address each member as cited in claim 9 for a prior art rejection. The examiner invites applicant to provide any factual evidence to show that claim 9 is not claimed in such a "too great in numbers" so as not to unduly burden the examiner to do a complete office action. Insofar as there is not any evidence to disprove the undue burden should claim 9 be examined in its full breadth, the examiner maintains that the species restriction is proper, and thus, made final.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

To the extent that applicant has not acknowledges on record that the priority French application is present in any of the parent case, or that the French priority document is not present or accessible for the examiner's consideration, claims 1, 2, 4, 10, 11, 12, as generically claimed, are rejected under 35 USC 103(a) as being anticipated by Ross (US Pat No. 6,444,799).

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Ross teaches a DNA vaccine composition comprising an adjuvant chosen from the polymers of acrylic or methacrylic acid and EMA (copolymers of maleic anhydride and alkenyl derivative) and a plasmid vector encoding a *P. gingivalis* polypeptide, e.g., column 2, lines 45-67, column 5 bridging column 6, and column 6, lines 27-37. As such, Ross does teach a method of employing the adjuvant to enhance the efficacy of the DNA vaccine *in vivo*.

Claims 1-13 are rejected under 35 USC 103(a) as being unpatentable over WO 98/03198 (translated by the English version of US Pat No. 6,207,166, which claims as a CIP of the '198 patent) taken with Miles Inc. (EP 0 532 833 A1), Lowell (WO 95/11700), and Lund (US Pat No. 3,920,811).

The '198 reference teaches a DNA vaccine composition comprising a plasmid encoding an antigen from either an equine rhinopneumonitis virus, EHV, or from equine influenza virus, EIV, and any traditional vaccine such as live or inactivated, recombinant or subunit EHV or EIV vaccine, which is used as a vaccine booster, e.g., page 4, lines 10-22, page 8, lines 11-25, which pages correspond to column 3, lines 24-35, and column 5, lines 51-57.

The '198 reference does not teach an incorporation of an adjuvant in the DNA vaccine composition used in horse so as to provide protection against a pathogen such as EHV.

However, at the time the invention was made, Miles Inc. teaches a combination vaccine comprising an adjuvant preferably a Carbopol acrylic-based adjuvant is effective for use in protecting horse against EHV (entire document, abstract, page 4, lines 18-22).

In addition, Lowell teaches that polymeric adjuvant including those of polyacrylic acid and/or polymethacrylic acid (e.g., CARBOPOL, CARBOMER) poly(methylvinyl ether/maleic anhydride) copolymer, and their mixtures and copolymers in a final concentration of 0.01-0.5% (w/v) are effective for use conferring bioadhesive properties, e.g., enhances the delivery and attachment of antigens on or through the target mucous surface conferring mucosal immunity (page 15).

Notwithstanding the teaching of Lowell as to the well-recognized use of polymer-based adjuvant

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in vaccine composition which provides an antigen in a subject in need of a vaccine, Lund also teaches that acrylic acid polymer adjuvant composition comprising a mixture of an acrylic acid polymer crosslinked with a polyallylsaccharide, e.g., polyallylpentaerythritol or polyallylsucrose, exhibit the properties which greatly enhance the ease with which they may be formulated with active agents in the production of therapeutic mixtures of the adjuvant composition and active agent, e.g., vaccine against EIV (abstract, column 3, lines 26 through column 4, column 9. In addition, the use of these polymer based adjuvant has been well-recognized in the prior art as being effective for boosting antibodies production and the controlled release of an active agent in a vaccinated animal (column 1 and 2).

It would have been obvious for one of ordinary skill in the art to have incorporated a polymer based adjuvant such as those described in the secondary references in a DNA vaccine composition of the '198 reference, which adjuvant not only boosts production of antibodies in a vaccinated animal, but also provides the control release and/or bioadhesive properties for any active agent contained in the DNA vaccine composition of the primary reference. One would have been motivated to do so because of the following teachings provided by the secondary references:

Miles Inc. teaches a combination vaccine comprising an adjuvant preferably a Carbopol acrylic-based adjuvant is effective for use in protecting horse against EHV (entire document, abstract, page 4, lines 18-22);

In addition, Lowell teaches that polymeric adjuvant including those of polyacrylic acid and/or polymethacrylic acid (e.g., CARBOPOL, CARBOMER) poly(methylvinyl ether/maleic anhydride) copolymer, and their mixtures and copolymers in a final concentration of 0.01-0.5% (w/v) are effective for use conferring bioadhesive properties, e.g., enhances the delivery and attachment of antigens on or through the target mucous surface conferring mucosal immunity (page 15); and

Lund also teaches that acrylic acid polymer adjuvant composition comprising a mixture of an acrylic acid polymer crosslinked with a polyallylsaccharide, e.g., polyallylpentaerythritol or polyallylsucrose, exhibit the properties which greatly enhance the ease with which they may be formulated

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with active agents in the production of therapeutic mixtures of the adjuvant composition and active agent, e.g., vaccine against EIV (abstract, column 3, lines 26 through column 4, column 9. In addition, the use of these polymer based adjuvant has been well-recognized in the prior art as being effective for boosting antibodies production and the controlled release of an active agent in a vaccinated animal (column 1 and 2).

Thus, the claimed invention as a whole was *prima facie* obvious.

Claims 1 and 14 are rejected under 35 USC 103(a) as being unpatentable over WO 98/03198 (translated by the English version of US Pat No. 6,207,166, which claims as a CIP of the '198 patent) taken with Miles Inc. (EP 0 532 833 A1), Lowell (WO 95/11700), and Lund (US Pat No. 3,920,811), and further in view of the admission by the specification (page 3) of the prior art which teaches the availability of EMA which is based on poly(methylvinyl ether/maleic anhydride) copolymers.

To the extent that the combined cited references which do not teach the use of commercially available adjuvants such as EMA which is produced based on poly(methylvinyl ether/maleic anhydride) copolymers, the rejection of the base claim is applied here as indicated above. One of ordinary skill in the art would have been motivated to employ any commercially available polymer-based adjuvant such as EMA in DNA vaccine composition taught by the combined cited references. One of ordinary skill in the art of polymer based adjuvant would have been motivated to employ EMA rather than just making one on the basis of the teaching of the combined cited references because of the ease and convenience of obtaining the adjuvants from the prior art and because of the availability of the adjuvants commercially.

Thus, the claimed invention as a whole was *prima facie* obvious.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

To the extent that claims 1 and 14 are readable on the recitation of a trademark named product, EMA®, the claims are indefinite because it is not apparent as to what are exactly the contents contained in the trademark named product, particularly since the trademark named product continues to evolve in its contents when produced by its manufacturer at any time.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **(703) 305-2024**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Deborah Reynolds*, may be reached at **(703) 305-4051**.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is **(703) 305-7401**.

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.

Dave Nguyen  
Primary Examiner  
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DAVE T. NGUYEN  
PRIMARY EXAMINER